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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,954

04/27/2005

Eckhard Floter

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EXAMINER

PADEN, CAROLYN A

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

04/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,954	Applicant(s) FLOTTER ET AL.	
	Examiner Carolyn A. Paden	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5-23-07</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim 8 provides for the use of folic acid, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation D3,3 is not understood and there is no basis for it in claim 1. Clarification is requested.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for phytosterol fatty acid ester, does not reasonably provide enablement for sterol fatty acid esters.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. It is not seen that cholesterol is contemplated as the sterol fatty acid ester of the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penteado (EP 1,155,699) in view of Suzuki (EP 1,180,545) taken with Wester (6,162,483).

Penteado discloses a nutritional composition of phytosterols, folic acid and other nutritional ingredients (abstract). The compositions are said to decrease cholesterol and homocysteine in the blood and therefore can be used for treatment of conditions related to heart disease (page 2, paragraph 0002). The ingredients of the composition are shown on page 3, paragraph 0033 to fall within the range of the claims and also include vitamin B6 and B12. The composition is made, as shown on page 4, paragraph 0040, by mixing all of the dry ingredients together with water and

fat and extruding it. The use of the composition in emulsions is mentioned as an alternative use of the product in paragraph 0042. The claims appear to differ from Penteado in the recitation of the inclusion of phytosterol esters or sterol fatty acid esters in the product. Suzuki discloses that vegetable sterol esters are more soluble in fat and oil than unesterified plant sterols (page 2, paragraph 0009). At page 16, column 0104 the application of the product to margarines and spread is suggested. It would have been obvious to one of ordinary skill in the art to substitute the phytosterol ester of Suzuki for the phytosterol of Penteado in a margarine emulsion in order to create a healthy spread with a solublized phytosterol ester. It is appreciated that the amount of oil and the kind of emulsion is not mentioned but margarines are known in the art to be water in oil emulsion with a lot of fat in them and Wester is relied upon to support this assertion. It is also appreciated that the process of combining the ingredients is not mentioned but Penteado does not disclose any criticality in the order of mixing. To mix the water soluble ingredients with water and the fat soluble ingredients with fat would have been an obvious way to combine the ingredients.

Wester discloses the use of phytosterol esters in margarine (see abstract and examples). The extent of fat in the composition The claims appear to differ from Wester

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn A Paden whose telephone number is (571) 272-1403. The examiner can normally be reached on Monday to Friday from 7 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached by dialing 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

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access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Carolyn Paden/

Primary Examiner 1794